

**REMARKS**

Entry of the foregoing, reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. §1.112, are respectfully requested in light of the remarks which follow.

**I. Claim Amendments**

By the foregoing amendment, claims 1 and 4 have been amended. Support for the amendments to the claims may be found throughout the specification and claims as-filed. The amendments to the claims have been made without prejudice or disclaimer to any subject matter canceled herein. Applicants reserve the right to file one or more continuation and/or divisional applications directed to any canceled subject matter. No new matter has been added, and entry of the foregoing amendments of the above-identified application are respectfully requested.

**II. Response to Rejection Under 35 U.S.C. § 112, Second Paragraph**

Claims 1-8 and 16 stand rejected under 35 U.S.C. 112, second paragraph as purportedly indefinite. Claims 1-2 and 5-6 stand rejected for the recitation of "HLB". Independent claim 1 is amended herein to recite "hydrophilic-lipophilic balance", spelling out "HLB".

Claim 4 stands rejected for the recitation of "such as". Claim 4 is amended to remove this language.

Accordingly, Applicants request that these rejections be withdrawn.

**III. Claim Rejections Under 35 U.S.C. § 103**

Claim 1-8 and 16 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsson et al. (US 5,015,576) and/or Nilsson et al. (US 4,935,365) in view of Morse et al. (US 4,123,382).

Initially it should be noted that M.P.E.P. § 2142 provides that to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach

or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991), under 35 U.S.C. 103, the examiner must provide evidence which as a whole shows that the legal determination sought to be proved (*i.e.*, the reference teachings establish a *prima facie* case of obviousness) is more probable than not.

Independent claim 1 recites a method for preparation of a porous gelatin material in the form of spheres with a continuous pore structure, comprising preparing a homogeneous water-based gelatin solution, adding an emulsifier with an HLB value of >9, adding a first composition comprising an organic solvent and an emulsifier with an HLB value >9, and adding a second composition comprising an organic solvent and an emulsifier with an HLB value <8. Nilsson ('576) or Nilsson ('365) in combination with Morse do not disclose or suggest the present invention.

In both Nilsson ('576) and Nilsson ('365), a solution of gelatin is mixed with an emulsifier having an HLB of >9. A solution of organic solvent containing an emulsifier with an HLB of <8 is added to the gelatin solution. The gelatin solution is saturated with the organic solvent. As an emulsifier with an HLB of >9 stabilizes emulsions of organic solvent in water, the droplets of organic solvent will be stabilized in the gelatin solution. Addition of further organic solvents containing an emulsifier with an HLB of <8 creates a system consisting of gelatin droplets in the organic phase. An emulsifier with an HLB of <8 stabilizes emulsions of aqueous solutions on organic solvents. These gelatin droplets contain droplets of the first added organic phase. The system is cooled down below the gelatin point of gelatin and the structure is conserved. Thus, it is the first addition of the organic phase which creates the porous structure.

In contrast to Nilsson ('576) and Nilsson ('365), in the method of the present invention a solution of gelatin is mixed with an emulsifier having an HLB of >9. A solution of organic solvent containing an emulsifier with an HLB of >9 is added to the gelatin solution. Applicants assert that the resulting system is unexpected, as the claimed methods unexpectedly create a highly porous structure having interconnected pores.

Specifically, the claimed method of the present invention creates a system having two continuous phases, one aqueous and one organic phase (in contrast to merely creating droplets of organic phase in the gelatin solution). It is the combination of gelatin solution containing an emulsifier with an HLB of  $>9$  together with a solution of organic solvent containing an emulsifier with an HLB of  $>9$  that creates the *unexpectedly* highly porous structure with interconnected pores. The structure of the present invention may be formed into different shapes through solidification in molds of different shapes. For example, the structure can be shaped into spheres by adding a solution of organic solvent containing an emulsifier with an HLB of  $<8$ .

Morse merely discloses the making of gelatin capsules using cyclohexane, and does not remedy the deficiencies of Nilsson ('576) and Nilsson ('365). Thus, Nilsson ('576) and Nilsson ('365) as combined with Morse does not teach or even suggest a method for preparation of a porous gelatin material in the form of spheres with a continuous pore structure using an emulsifier with an hydrophilic-lipophilic balance value of  $>9$ , a first composition comprising an organic solvent and an emulsifier with an HLB value  $>9$ , and then a second composition comprising an organic solvent and an emulsifier with an HLB value  $<8$ .

In light of the above, Applicants request that this rejection be withdrawn.

**CONCLUSION**

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

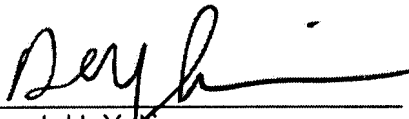
In the event that there are any questions relating to this Amendment and Reply, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney at 703-838-6563 concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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